K022567

AUG 1 3 2002

510(k) SUMMARY

Sequoia Diagnostic Ultrasound System Signature II

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with the Safe Medical Device Act of 1990 revisions to 21 CFR, Part 807.92, Content and Format of a 510(k) Summary.

1. **Submitted By:**

Acuson Corporation
1220 Charleston Road
PO Box 7393
Mt. View, California 94039-7393

Contact Person
Mr. Jerry W. Tsutsumi
Regulatory Affairs Department
Phone: (650) 943-7286
Fax: (650) 961-6168

Date Prepared
26 June 2002

2. **Proprietary Name:**
Sequoia Diagnostic Ultrasound System Signature II

Common/ Usual Name:
Diagnostic Ultrasound System with Accessories

Classification Name:
21 CFR 892.1550

Ultrasonic Pulsed Doppler Imaging System	FR# 892.1550	Product Code 90-IYN
Ultrasonic Pulsed Echo Imaging System	FR# 892.1560	Product Code 90-IYO
Diagnostic Ultrasound Transducer	FR# 892.1570	Product Code 90-ITX
Diagnostic Intravascular Catheter	FR# 870.1200	Product Code 90-DQO

3. **Predicate Device:**
K935595/S1 (3/2/1995) cleared as Model 3001 system, marketed as the Sequoia diagnostic ultrasound system with subsequent modifications.

4. **Device Description:**
The Sequoia is a general purpose, mobile, software-controlled, diagnostic ultrasound system with an on-screen display for thermal and mechanical indices related to potential bioeffect mechanisms. Its function is to acquire primary or secondary harmonic ultrasound echo data and display it in B-mode, M-mode, Pulsed (PW) Doppler mode, Continuous (CW) wave Doppler mode, color Doppler mode, Power Amplitude Doppler mode, a combination of these modes, Harmonic Imaging, or 3D imaging, on a CRT display.

The Sequoia system has been designed to meet the following product safety standards:

- UL 2601-1, Safety Requirements for Medical Equipment
- CSA C22.2 No. 601-1, Safety Requirements for Medical Equipment
- AIUM/NEMA UD-2, 1998, Acoustic Output Measurement Standard for Diagnostic Ultrasound
- AIUM/NEMA UD-3, 1998, Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- 93/42/EEC Medical Devices Directive
- Safety and EMC Requirements for Medical Equipment
  - EN 60601-1

  - EN 60601-1-1
  - EN 60601-1-2
- IEC 1157 Declaration of Acoustic Power
- ISO 10993 Biocompatibility

5. Intended Uses:

The Sequoia system is intended for the following applications: General Imaging and Cardiology for Fetal, Abdominal, Intraoperative (abdominal and neurological), Pediatrics, Small Organs (breast, testes, thyroid, penis and prostate), Neonatal/Adult Cephalic, Cardiac (adult, pediatric and neonatal), Trans-esophageal, Transrectal, Transvaginal, Peripheral Vessel, and Musculo-skeletal (Superficial and Conventional) applications.

The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

The AcuNav diagnostic ultrasound catheter is intended for intra-cardiac and intra-luminal visualization of cardiac and great vessel anatomy and physiology, and visualization of other devices in the heart – for use in the right heart only.

6. Technological Comparison to Predicate Device:

The Sequoia is substantially equivalent to Model 3001, K935595/S1/S1, and to products that are already cleared for USA distribution with the following 510(k) premarket notification numbers K973767, K992580, K992631, K002807, K991805, and K002470. All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate on-screen display of anatomic structures and fluid flow within the body. All systems allow for specialized measurements of structures and flow, and calculations.

End of 510(k) Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 2002

Acuson Corporation
% Mr. Mark Job
Program Manager
TÜV Product Service
1775 Old Highway 8 NW, Suite 104
NEW BRIGHTON MN 55112-1891

Re: K022567
Trade Name: Sequoia® Diagnostic Ultrasound System Signature II
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic ultrasonic transducer
Regulatory Class: II
Product Code: 90 IYN, IYO, and ITX
Dated: August 1, 2002
Received: August 2, 2002

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Sequoia® Diagnostic Ultrasound System Signature II, as described in your premarket notification:

Transducer Model Number
4C1
5C2

6C2
8C4
EC10c5
EV8C4
6L3
AcuNav (IC10V5)
8L5
8L5T
13L5SP
15L8
15L8w
V5M TEE
V7M TEE
V7B TEE
Sirius
3V2c
4V1
4V2
5V2c
7V3c
8V5
10V4
AUX CW

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

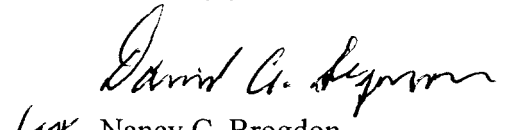
Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,



for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Page 1 of 1

510(k) Number (if known): K022567

Device Name: Sequoia Diagnostic Ultrasound System Signature II

Indications for Use:

The Sequoia system is intended for the following applications: General Imaging and Cardiology for Fetal, Abdominal, Intraoperative (abdominal and neurological), Pediatrics, Small Organs (breast, testes, thyroid, penis and prostate), Neonatal/Adult Cephalic, Cardiac (adult and pediatric), Trans-esophageal, Transrectal, Transvaginal, Peripheral Vessel, and Musculo-skeletal (Superficial and Conventional) applications.

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-the-Counter-Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

David A. Segman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022567